

**Application No.:** 10/789,589  
**Filing Date:** February 27, 2004

### **AMENDMENTS TO THE DRAWINGS**

Clerical errors have been noted in the labeling of Figure 1. The indication of Polyacetal-GLP (1-6)-His, Polyacetal-Mel (head), and Polyacetal-Mel (head)-Cys has been amended to "Polyacetal-GLP-(1-6)-H, Polyacetal-Mel (head)-QQ, and Polyacetal-Mel-(head)-QQ-Cys". Support for the amendment is found in Example 4, paragraph 0058. Both a replacement sheet and a clean version replacement sheet are submitted herewith in the Appendix.

### **REMARKS**

The specification has been amended to show the second occurrence of "Example 6" as "Example 7" and to correct "PEI-1800 (negative control) to PEI-600 (negative control)" in paragraph 0061. Support is found in Figure 6 and within paragraph 0061 which refers to "commercial agent poly(ethylenimine)-600 daltons".

Claims 2, 4-6, 8, 15, and 18-20 have been cancelled. Claims 1, 3, 7, 9, 12-14, 16, and 21 have been amended. Claims 1, 3, 7, 9-14, 16-17, and 21-27 are now pending in this application. Claims 9-10, 12-14, 16-17, and 21-27 are withdrawn. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### **Restriction/election**

The Examiner's withdrawal of the restriction between Groups I and II and indication that the Formulae I-IV and SEQ ID NO: 1 are free of the art is gratefully acknowledged. Claims 1-7 and 11 have been examined. Applicants respectfully request rejoinder of claims 9-10, 12-14, 16-17, and 21-27. Claims 9-10, 12-14, 16-17, and 21-27 have been amended to be commensurate in scope with amendments to Group II claims.

#### **Claim objections**

Claim 6 is objected to for the recitation of "X" and "Y".

This objection is moot in view of Applicants' cancellation of claim 6.

#### **Rejection under 35 U.S.C. § 101**

Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

This ground of rejection is addressed by amendment of claim 1 to specify that the polynucleotide is "an isolated DNA".

In view of Applicants' amendment, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 112, first paragraph – written description**

Claims 1-7 and 11 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time that the application was filed.

This ground of rejection is addressed in part by amendment taken with Applicants' comments below.

The Examiner states that the claims encompass several classes of polynucleotides. In response, Applicants have amended the claims to specify DNA. As noted by the Examiner, transfection using DNA is shown in the Examples and Figures. One skilled in the art would reasonably expect that any DNA could be transfected by the transfection agents (the polyacetal-peptide) disclosed in the specification. For example, Superfect® and Lipofectamine 2000®, commercially available transfection agents, are used for comparison in the Examples of the specification (see Figures 1 and 5). Both of these reagents transfect DNA generally as evidenced by the product descriptions provided as Attachments A and B. These attachments evidence that reagents similar to the claimed polyacetal-peptides transfect not just specific DNA, but DNA generally. The DNA used in the Examples of the specification is a reporter plasmid used so that the transfection can be tracked and the transfection efficiency quantitated. However, one skilled in the art would recognize that the utility is not limited to the specific reporter genes which were transfected to show the effectiveness of the claimed polyacetal-peptides. One skilled in the art would reasonably expect the transfection agents according to the invention to also be applicable to DNA generally.

In further support of this position, claim 1 has been amended to recite a composition comprising the polyacetal-peptide rather than a complex which includes both a polynucleotide and the polyacetal-peptide transfection agent. The polyacetal-peptide may be used with any DNA.

The Office Action also asserts that there is insufficient written description for polyacetal-peptides as claimed as only one polyacetal-peptide is exemplified in the specification.

Applicants respectfully point out that at least three of the peptides disclosed by Applicants were effective transfection agents as polyacetal-peptides. The Examiner's attention is directed to Figure 1 and Example 4 (paragraph 0058, substitute specification of May 15, 2007)

which discloses successful transfection using polyacetal-peptides where the peptide was GLP (1-6)-His (SEQ ID NO: 8), Mel-head-QQ (SEQ ID NO: 5) or Mel-head-QQ-Cys (SEQ ID NO:6). A further experiment using GLP (1-6) H is described in Figures 5 and 6 and paragraphs 0060-0061 of the substitute specification submitted May 15, 2007. Accordingly, the claims have been amended to recite specifically these three polyacetal peptides. Applicants respectfully submit that there is adequate written description based upon the Examples and Figures discussed above for the amended claims.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

#### **Rejections under 35 U.S.C. § 102**

Claims 1-4 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Kakizawa, (2001, Biomacromolecules, 2, 491).

Claims 1-4 are rejected under 35 U.S.C. § 102 (a) as being anticipated by WO 03/078576A2 (Yu, et al.) as evidenced by Terwilliger, et al. (Biophys. J., 1982, 37, 353).

Both of the above grounds of rejection are addressed by Applicants' claim amendments. Claims 5 and 6 have been incorporated into claim 1.

In view of Applicants' amendments, reconsideration and withdrawal of the above grounds of rejection is respectfully requested.

#### **Double patenting**

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending application No. 10/946,383.

This ground of rejection is addressed by incorporation of claims 5 and 6 into claim 1.

In view of Applicants' amendment, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this

**Application No.:** 10/789,589  
**Filing Date:** February 27, 2004

application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**Co-Pending Applications of Assignee**

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee (Entry in **BOLD** is the present application).

Serial Number	Title	Filed
10/341,059	SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY	13-Jan-2003
<b>10/789,589</b>	<b>COMPOSITIONS AND METHODS FOR BIODEGRADABLE POLYMER-PEPTIDE MEDIATED TRANSFECTION</b>	<b>27-Feb-2004</b>
10/800,934	METHODS FOR EXTENDING AMORPHOUS PHOTOREFRACTIVE MATERIAL LIFETIMES	15-Mar-2004
10/876,322	REVERSE SYNTHETIC METHODS FOR MAKING ORGANIC NON-LINEAR OPTICAL MATERIALS	24-Jun-2004
10/884,530	PHOTOCLEAVABLE DNA TRANSFER AGENT	02-Jul-2004
10/946,383	BIODEGRADABLE POLYACETALS FOR IN VIVO POLYNUCLEOTIDE DELIVERY	21-Sep-2004
10/954,756	IMAGE CORRECTION DEVICE	30-Sep-2004
10/980,079	MICROSCOPE SYSTEM AND METHODS FOR INTRACELLULAR STUDIES	03-Nov-2004
11/126,878	BIODEGRADABLE POLYACETALS AND METHODS	10-May-2005
11/134,820	HYDROPHILIC POLYMERS WITH PENDANT FUNCTIONAL GROUPS AND METHOD THEREOF	19-May-2005
11/216,986	BIODEGRADABLE CATIONIC POLYMERS	31-Aug-2005
11/219,145	TRANSEPITHELIAL DELIVERY OF PEPTIDES WITH INCRETIN HORMONE ACTIVITIES	02-Sep-2005
11/251,956	INTRACELLULAR PEPTIDE DELIVERY	17-Oct-2005

**Application No.:** 10/789,589  
**Filing Date:** February 27, 2004

11/255,735	(METH)ACRYLATE POLYMER AND NON-LINEAR OPTICAL DEVICE MATERIAL COMPOSITION	21-Oct-2005
11/286,243	VECTOR FOR TRANSFECTION OF EUKARYOTIC CELLS	23-Nov-2005
11/303,082	SOLID SURFACE WITH IMMOBILIZED DEGRADABLE CATIONIC POLYMER FOR TRANSFECTING EUKARYOTIC CELLS	14-Dec-2005
11/359,811	POLYMER COATING OF CELLS	22-Feb-2006
11/360,161	PHOTOREFRACTIVE COMPOSITION	23-Feb-2006
11/364,596	CONTROLLABLY DEGRADABLE POLYMERIC BIOMOLECULE OR DRUG CARRIER AND METHOD OF SYNTHESIZING SAID CARRIER	27-Feb-2006
11/525,482	PEPTIDE NUCLEIC ACID BASED GUANIDINIUM COMPOUNDS	21-Sep-2006
11/525,512	MULTI-VALENT GUANIDINIUM COMPOUNDS FOR ENHANCING MOLECULAR TRANSLOCATION ACROSS CELLULAR MEMBRANES AND EPITHELIAL TISSUES	21-Sep-2006
11/526,224	GUANIDINIUM DELIVERY CARRIERS	22-Sep-2006
11/526,927	SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY	26-Sep-2006
11/527,134	SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY	26-Sep-2006
11/566,141	POLYGLUTAMATE-AMINO ACID CONJUGATES AND METHODS	01-Dec-2006
11/613,895	METHOD FOR PRODUCING CARBON NANOTUBES, METHOD FOR PRODUCING LIQUID DISPERSION THEREOF AND OPTICAL PRODUCT	20-Dec-2006
11/615,831	TRANSPARENT ELECTRICALLY-CONDUCTIVE HARD-COATED SUBSTRATE AND METHOD FOR PRODUCING THE SAME	22-Dec-2006
11/695,365	BIODEGRADABLE CATIONIC POLYMERS	02-Apr-2007
11/747,624	LIGHT EMITTING DEVICES AND COMPOSITIONS	11-May-2007
11/781,508	NON-LINEAR OPTICAL DEVICE WITH LONG GRATING PERSISTENCY	23-Jul-2007
11/781,633	NON-LINEAR OPTICAL DEVICE SENSITIVE TO GREEN LASER	23-Jul-2007

## **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the

**Application No.:** 10/789,589  
**Filing Date:** February 27, 2004

Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Nov. 15, 2007

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